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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,667	02/15/2002	Ralph Scannell	98,710-B	5122

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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937667

Applicant(s)

Scannell et al

Examiner

J. M. Ford

Group Art Unit

1624

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-24 are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
 - ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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The claims in the application are claims 1-24.

This is a 371 application. Content in 371 applications is controlled by 37 CFR 1.1475. Rule 475 makes it clear that once a compound claim is determined to have allowable language that applicants are entitled to have, at most one product, one use of those compounds and one method of making those compounds; provided the claims are all of the same scope.

Claim 1 is directed to two products. G¹ being carbon or nitrogen. Claim 1 should be re-written to one product.

Claims 22--24 are not directed to one disease. The claims need to be to a Pharmaceutical composition, and a method of treating a Real World Disease.

The recent utility guidelines set by the U.S.P.T.O. require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which require that utility be developed to appoint where "specific benefits exist in currently available form." Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880, refers to. The standard set forth in the concurring opinion of ~~In~~ re Hartop, 135 USPQ 419, is whether the invention has been brought to such perfection as to be capable of practical employment. This language is echoed in Brinda vs. Kelly, 206 USPQ 570.

The PTO has amended the guidelines to clarify "specific utility". The court focused on the need to identify a "Specific ~~Utility~~" in Brenner v. Manson.

Patents are issued by the Commerce Dept. to stimulate Commerce. The Court (Brenner vs. Manson) reasoned that the utility should relate to the Real

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World of Commerce, that would be understandable, not a broad recitation of many possible diseases.

A one page "Abstract" is requested, that has no other information on the page.

This is a 371 application, Content of a 371 application is governed by Rule 475. If multiple product are claimed, G¹=carbon or G¹=nitrogen, applicants are required to elect one. If multiple methods of utility are presented, applicants are required to elect one.

UNITY OF INVENTION

1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention if the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- ➔ (1) A product and a process specifically adapted for the manufacture of said product; or
- ➔ (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17 (3)(a) and 1.476 (c).

- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

This is a 371 application, 37 CFR 1.475 requires applicants elect one utility.

It would not be a reasonable burden on the Examiner to try to examine all of the claims here. 37 CFR 1.475 and PCT Rule 13.2 make it clear that in addition to the elected single Invention compounds, the applicant may have one, clear, specific use of their compounds examined therewith. Applicants need to elect one such specific, demonstratable, World of Commerce disease.

It would require undue experimentation to determine what host-dosage relationship would produce what result.

A broad claim of utility as in claims 22--24 cannot be deemed in compliance with 35 U.S.C. 112, first paragraph.

The Court focused on the fact that the applicant failed to identify a "specific utility" in *Brenner v. Manson*.

This application has been found to contain more than one invention. Therefore, restriction to one of the following distinct inventions is required:

- (I) Claims 1----20 where G¹ is a carbon value, a piperidine in class 546
- (II) Claims 1----20 where G¹ is a nitrogen, a piperazine in class 544
- (III) Claims 21—24 drawn to a composition and multiple methods in

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class 514.

These distinct inventions have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Accordingly, restriction for examination purposes, as indicated, is considered proper; 35 U.S.C. 121; 37 CFR 1.475.

Claim 1 constitutes an improper joinder of inventions as it groups together species inventions that are distinct and separately classified, and will support separate patents. Ex parte Markush, 1925 C.D. 126, provided for this claim structure where there was an emergency engendered need, as the substances were "so closely related that they would not support a series of patents". This is not the case here. Therefore, the instant generic claims constitute an improper joinder of inventions; Ex parte Reid, 105 U.S.P.Q. 251; In re Winnek, 73 U.S.P.Q. 225; In re Ruzicka, 66 U.S.P.Q. 226.


Applicants' response must include a provisional election, even if the requirement be traversed, see 37 CFR 1.499.

Applicants' should elect Group I or Group II.

Once a generic claim to the elected invention is found allowable, claim 21 will be recombined, and one method of use from claims 22—24. Claims 22---24 should be rewritten to one specific, demonstratable, method of use, per 37 CFR 1.475.

John M. Ford:tgd

December 12, 2003


JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624